



Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2001-DT-25

July 23, 2001

Mark K. Baumeier, D.O.
Mammography Supervisor
McPherson Hospital
620 Byron Road
Howell, MI 48843

Dear Dr. Baumeier:

We are writing you because on July 12, 2001, your facility was inspected by a representative of the State of Michigan, acting in behalf of the Food & Drug Administration (FDA). The inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following Repeat Level 2 finding at your facility:

1. One (1) of five (5) random medical reports reviewed did not contain an acceptable assessment category.

The specific problem noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which your facility received at the close of the inspection. This problem is identified as a Repeat Level 2 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement permanent corrective action of this problem found during your previous inspection.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of law

which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 and Repeat Level 3 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 and Repeat Level 3 findings are:

1. Corrective action before further exams, for a failing image score, or a phantom background optical density, or a density difference outside the allowable regulatory limits was not documented for the [REDACTED] unit in Room 2.
2. Failed to produce documents verifying that the radiologic technologist, [REDACTED] met the continuing experience requirement of having performed 200 mammography examinations in 24 months.
3. The required personnel documents were not available during the inspection. This is a Repeat violation from your previous inspection.

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the Repeat Level 2, Level 2 and Repeat Level 3 violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- Sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

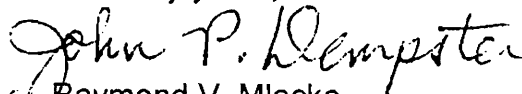
Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U.S. Food and Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent State requirements, if any. You should also send a copy to the State of Michigan radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and any additional State requirements in your response.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,


for Raymond V. Mlecko
District Director
Detroit District

Enclosures:a/s